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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,335	04/09/2004	Paul D. Wightman	58562US005	9992

32692 7590 02/27/2006

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,335	WIGHTMAN ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *10 and 15-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/06,8/04,4/18/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2/15/06* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-, 9, 11-14 in part, drawn to IRM-support complex wherein the IRM compound is an imidazoquinoline amine, a imidazonaphthyridine amine or an imidazopyridine amine, classified in class 546, subclass 82,118,293,300.

II. Claims 1-14 in part , drawn to an IRM complex wherein the IRM compound one given in claim 7 and is other than given in group I, classified in various classes and subclasses. A further election of a single disclosed species is required. This group may be subject to further restriction.

III. Claims 15-23, drawn to medical articles coated with the IRM complex covalently attached to a polymer, classified in various classes and subclasses.

IV. Claims 24-27, drawn to formulations of these IRM-support complex attached to a macromolecular support, classified in various classes and subclasses.

V. Claims 28-31, drawn to a method of making these IRM complexes, classified in various classes and subclasses.

VI. Claims 32-51 , drawn to various methods of treating using these compounds, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation,

and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different IRM compounds , which have a different structure and bonding.

Inventions I, II and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case applicants own compounds in group I and II are a different group of compounds made by same process, i.e. the process can be used to make different compounds.

Inventions I, II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case other drugs available in the market can bring about the method of treating a viral response or restenosis.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Christopher Gram on 2/10/06 a provisional election was made with traverse to prosecute the invention of Group I , claims 1-9, 11-14 in

part, drawn to IRM-support complex wherein the IRM compound is an imidazoquinoline amine, a imidazonaphthyridine amine or an imidazopyridine amine . Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art , the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Rejoinder :-

The examiner has required restriction between product and process claims . Where applicants elects claims directed to the product , and a product claim is subsequently found allowable , withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to the final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of a rejoinder , the requirement for restriction between the product claims and the rejoined process claims will be withdrawn , and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. thus to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable , an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See " Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally , in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product or have all the limitations of the product claim.

Failure to do so may result in a loss of the right to rejoinder.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims1-6, 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to compounds that is an agonist of atleast one TLR and also that the IRM is a small molecule immune response modifier. The specification defines on pages 15 describes in words some compounds stating that they are TRL6 or TRL7 or TRL8 agonists. **The specification gives no evidence that it is so.**

The expression "*a macromolecular support material and TLR agonists and immune response modifier and a macromolecular support material has an average largest dimension of atleast 1nm.***" does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement for the expression "***a macromolecular support material and TLR agonists and immune response modifier , and a macromolecular support having an average largest dimension of atleast 1nm.***" as one of ordinary skill in the art could not recognize or understand which diseases /disorders are treated by the mere recitation of the function. Claims employing functional language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the**

monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an *invitation to experiment* ***regarding possible small molecules which may be TLR agonist and are immune response modifiers.***

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4689338 Gerster et al.

The reference discloses the imidazoles of the applicants claims with a macromolecular support. (polyethylene glycol)

Applicants specification on page 21 clearly states that the support can be polyethylene glycol and that the IRM compound can be blended or dissolved in it.

The reference teaches the same compounds and their formulations in polyethylene glycol. See lines 20-25 column 8 of the reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim27-29, 35-40 of copending Application No. 10/821,330, claims 1-29 of co-pending application 10/821319, claims 1-16 of co-pending application 10/978850, claims 1-45 of US 10/640904 Although the conflicting claims are not identical, they are not patentably distinct from each other because they essentially either claim the same IRM compounds on a macromolecule .

US 10/640,904 teaches the compounds and an antigen. The antigens as described on page 7 of the '904 application , can be peptides , polypeptides, lipids, and such. These are all macromolecules which fall within the definition as given by the applicants see the paragraphs bridging the pages 7 and 8 of the application.

US 10/821330 claims 1, 27-29, 35-40 uses the same compounds and IRM depot preparations which would read on the complex of the invention. See pages 2 and 3 of the '330 specification, which includes polymers and also gives the size of the support molecule to be atleast 1nm.

US 10/978850 claims 1-16 are drawn to a method, however they teach using the same complexes. See page 12 lines 10-20. The macromolecular support system is cream, ointment, gel, lotions and the like.

US 10/821319 , claims 1-29 are also drawn to a complex on a support which has atleast one metal , this metal can be on a polymer see paragraphs bridging page 2 and 3 of the specifications.

US 6245776 claims 1-3 are also drawn to the same IRM compounds and macromolecules. They are made by the same way. The close proximity would inherently make hydrogen bonds between the compounds and the various substrates. See the claims and the specifications. A carbomer helps in the formation of a gel. See the specifications.

All these above applicants have the same compounds on a macromolecular support material.

Claim 1-9, 11-14 directed to the same invention as that of claims of commonly assigned above applications. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4689338 Gester

.WO 03/045391 Raymond Skwierczynski et al

US 6245776 Scwierczynski et al

Applicants invention is drawn to a complex of an IRM compound and a macromolecular support. The specifications defines the macromolecular support to be a large size molecule atleast 1nm in size and be covalently or non-covalently bonded. On page 8 the definition is given as below

In an IRM-support complex an IRM is attached to a macromolecular support material. As used herein, the term "attached" includes both covalent bonding and non-covalent chemical association (e.g., ionic bonding and hydrogen bonding) of an immune response modifier with a macromolecular support material. Non-covalent association is preferably by specific, high affinity protein–ligand interaction, as opposed to nonspecific hydrogen bonding. Preferably, the immune response modifiers are attached to a macromolecular support material by means of covalent bonding. The terms "coupled," "conjugated," "bonded," or "immobilized" may also be used herein to

Thus a Hydrogen bonding is included.

On page 21 the specifications describes how these complexes are made and it inclus mixing and blending. See lines 16-20.

Again, however, for many embodiments described herein it is important to note that the IRM is not simply dissolved or blended into a formulation from which it is to be released, but is attached to the support material by a sufficiently strong bond (which sometimes may require a covalent bond) so that under the circumstances of intended use the IRM is biologically active during use while it is attached to the support. Preferably, for certain embodiments (e.g., for bioadhesive polymeric support materials), the IRM is covalently attached to the support material. It should also be understood, however, that for each of the uses (e.g., medical articles such as stents or other implantable devices or extracorporeal devices) described herein an IRM may be provided in an unattached, releasable form, or become unattached over time, so that the IRM can be released and function in that manner. That is, for example, the IRM can be simply dissolved or blended into a macromolecular support material (e.g., as in a polymeric coating). Mixtures of the two types can also be used where desirable.

Gels, creams, films, salves, coatings, sticks, colloids, pastes, and foams incorporating IRM-support complexes can be applied to a variety of bodily surfaces, and among the many uses may include, e.g., wound dressings and wound packing materials. These sorts of solid, semi-solid, or viscous preparations can serve to promote the retention of the IRM compounds on the bodily surface and also to prevent the systemic adsorption of the IRM. Bodily surfaces can include, but are not limited to,

Determination of the scope and content of the prior art (MPEP §2141.01)

The Gester reference teaches the same compounds in gels , ointments , polyethylene glycol. The compounds are well mixed into the substrate in the same way as applicants mix theirs. See lines 20-25 column 8 of the reference.

The WO '391 reference teaches a variety of formulations. Specifying the same different IRM modifiers and different formulations .

US 6245776 Scwierczynski et al also teaches the same compounds and large molecules such as fatty acids and ethylene glycol and the IRM compound is solubilized in it. See colum 14, 15 . methylparaben is also used

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The prior art do not specifically use the words of the applicants, however inherently the complexes formed are the same since the same reagents and process is used.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Since the prior art reference uses the same compounds and the same substrates and mix and blend in the same way as those of the applicant the same complex are formed. Thus one of skill in the art would be motivated to use different words to define the same composition (complexes) as those of the invention.

Conclusion

Claims 1-9, 11-14 are rejected.

Claims 10, 15-51 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
February 15, 2006